REMARKS

Reconsideration and further examination of this application is respectfully requested. Claims 1-25 were originally presented for examination. Claims 1-8 and 18-25 have been withdrawn from prosecution, and Claims 9, 12 and 16 have been amended. Claims 10, 11, 13, 14, 15 and 17 are presented without further amendment.

Claims 9, 12 and 16 were objected to because of informalities, all which have been corrected by amendment and are shown in the listing of claims beginning on page 2 of this paper. No new material has been added.

Claims 9-17 were rejected under 35 USC § 102(b), as being anticipated by Rulcker et al. (1981). The Examiner states that "Rulcker teaches a method for treating joints of an animal, wherein the method comprises injecting synovial fluid obtained from another animal into the synovial joint of the animal in need thereof (page 264)." Additionally, the Examiner states that "[A]lthough Rulcker does not teach the method wherein the synovial fluid is made by the claimed process, these limitations are considered to be product by process type limitations.... In the instant case, the method of the prior art is the same as that claimed. Thus the methods differ only in how the synovial fluid is produced."

It is clear by reading of Rulcker that the method of treatment used in this study does not comprise injecting synovial fluid obtained from another animal into the synovial joint of the animal in need. The method of Rulcker is a simple technique of synovial fluid transfer between a "donor joint" and a "recipient joint" of the same animal. All references made to joints in the Rulcker paper refer to "donor joint" and "recipient joint", not donor animal or recipient animal or even recipient. Rulcker fails to mention anywhere or even suggest the dangers or precautions necessary when directly transferring synovial fluid from one animal to another. These would include spread of infection, disease and pathogens as well as immunological rejection of the serum by the host animal. Since any of these dangers will typically produce a condition far more detrimental to health of the animal than the malady being treated, it would not be contemplated by a reasonable veterinary practitioner. The significant drawback of the Rulcker treatment is that it sacrifices one joint of the animal in order to treat another. By removing a significant amount of synovial fluid from a healthy joint (i.e., 4-10 ml), it is now compromised. Additionally, if there is localized infection, inflammation and/or contamination of the donor joint that is undetected, upon transfer of that serum to the recipient joint, the infection, inflammation and/or

contamination is also transferred. Rulcker therefore teaches away from the present application which does not sacrifice one joint to assist another in the same animal. The present application also eliminates the significant problems of joint contamination with synovial fluid that has not been processed to eradicate contaminants, pathogens and potential immunological antagonists. The present application additionally performs this in a manner which is not subject to nearly immediate degradation.

To further clarify, the present application describes the steps of processing the synovial fluid to create a replacement fluid. This includes the limitations (set forth in the specification and claims of the original application) of removing the impurities as well as the cellular and pathogenic components of the donor fluid. These processing steps, as well as the step of lyophilization, produce a replacement fluid which is materially different than synovial fluid obtained from another animal or the same animal. Thus, "replacement fluid" as described in Claim 9 is not the same or an obvious extension of the synovial fluid that is simply removed from one donor joint and placed in a recipient joint as described by Rulcker et al. (1981).

Rulcker et al. describe that "[T]he synovial fluid was immediately (less than 5 mins) transferred by injection into the affected (i.e., recipient) joint. The size of needles for withdraw and injection were 0.8 x 35 mm." In addition to the fact that the applicants claim "fluid obtained from another animal", this "transfer" mentioned in Rulcker, does not create a replacement fluid as described in the applicants' claims and specification. Rulcker merely shares raw, unfiltered and unadulterated joint serum and particulates of lesser than 0.8mm (needle size is the only exclusion described by Rulcker) between joints of a single animal, with no method to assess or regulate quality or content of the transfer fluid. It is further stated by Rulcker that: "[T]here is, at present, no practical method to assess the quality of synovial fluid" (page 265).

It is, therefore, clear that the processing and lyophilization steps in the applicants' claims are material and novel. It is well known that synovial fluid has a very limited shelf life, as admitted by Rulcker et al. (immediate transfer of less than 5 minutes), and that there has to date been no successful product developed since this publication that overcome this problem. In addition, by transferring raw, unfiltered and unadulterated joint serum and particulates into recipient joint, pathogens, such as bacteria, virus, fungi, and the like are readily shared between the animals and may cause more damage to the joint and animal than the malady being treated. Furthermore, free floating cells as well as immune system regulators and cytokines, which may

cause immunological rejection issues, are transferred along with the whole joint serum. In the applicants' method, impurities, particulates, cells and pathogens that are large enough to be filtered, are mechanically sieved or otherwise removed. All other pathogens (i.e., virus, and the like) are killed or inactivated (sterilized) by the lyophilization process, thereby providing a replacement fluid that is acellular, sterile, pathogen free, and in a form that can be stored for considerable periods of time without degradation.

Currently amended independent claim 9 clearly distinguishes from the Rulcker et al. reference. The Rulcker et al. reference fails to disclose intraarticularly injecting a replacement fluid in the joint space of said animal, said replacement fluid comprising synovial fluid that has been harvested from other animals and has been processed, lyophilized, packaged and reconstituted. Whereas the Examiner contends that such a limitation is disclosed in the Rulcker et al. publication, this reference discloses merely a raw biological serum transfer, within the same animal, with no steps to modify the fluid before injection to a recipient. The presently claimed invention, in contradistinction, has created a materially different replacement fluid which maintains novelty, functionality and necessity in the treatment of joint maladies.

In a similar fashion, independent Claim 10 describes a "purified synovial fluid" which is analogous to the "replacement fluid" of Claim 9 prior to lyophilization. This purified synovial fluid has been harvested from other animals and has been processed to remove impurities, cellular components and pathogenic components. It is then lyophilized to produce a fluid that is acellular, sterile, pathogen free, and in a form that can be stored for considerable periods of time without degradation.

Hence, amended independent Claim 9 and original independent Claim 10, specifically differentiate from the aforementioned disclosure of Rulcker et al. Clearly, there is no disclosure or suggestion, in any fashion, of creating a replacement fluid from other animals that has been processed to remove impurities, cellular components and pathogenic components, lyophilized, packaged and reconstituted.

Claim 13 further differentiates purified synovial fluid from serum found naturally in joints by "removing said higher density particles from a supernate of said synovial fluid; and, filtering said supernate to remove additional particulates".

In view of the above, this application is now considered to be in condition for allowance and such action is earnestly solicited.

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Respectfully submitted,

COCHRAN FREUND & YOUNG LLC

By: _____

Paul M. Thompson
Registration No. 52,286
2026 Caribou Drive, Suite 201
Fort Collins, CO 80525

Phone: (970) 492-1100
Fax: (970) 492-1101
Customer No.: 27479